Remarks

Status of Claims

Claims 2-4, 6, 7, 9, 11, 15, 16 and 19-27 are pending. Claim 1 and 17-18 have been cancelled. The support for the new claims 19-27 can be found, for example, in Examples 4 and 5 and at page 46, lines 4-6 and 19-27 of the specification. Note that some of the dosages recited in these claims are derived from the daily dosages recited in the specification. For example, if a patient is administered a total of 0.5 mg/kg body weight in one to four doses per day, each unit dose would be 8.75 to 35 mg, assuming an average body weight of 70 kg. Likewise, at 10 or 20 mg/kg body weight, each unit dose would be 175 to 700 mg, and 350 to 1,400 mg, respectively.

Rejection Under 35 U.S.C. § 112, First Paragraph

Reconsideration is respectfully requested of the rejection of claims 1-4, 6, 7, 9, 11, and 15-18 under 35 U.S.C. § 112, first paragraph. These claims were rejected on the basis that they do not satisfy the written description requirement.

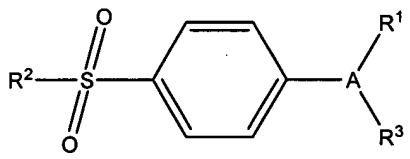
In particular, the Office alleged that the claims are drawn to a broad genus of compounds that include an infinite number of COX-2 selective inhibitors and selective LTB_4 receptor antagonists, "wherein no distinguishing structural attributes and/or identifying characteristics are provided other than the purely 'functional language' that is used to name the compounds (i.e. their ability to 'inhibit' or 'antagonize')."

Applicants have cancelled claims 1, 17 and 18, thereby rendering the rejection of these claims moot.

With respect to claims 2 and 9, they are directed toward a combination of a selective LTB_4 receptor antagonist, and a COX-2 selective inhibitor described structurally. Applicants establish possession of the invention because the specification provides a) identifying structure for more than 40 LTB_4 receptor antagonists within the scope of the claim, and b) the verbatim "structural chemical formula" for the COX-2 inhibitor of the claim. Thus, claims 2 and 9 satisfy

the written description requirement. Claim 11 is directed towards a combination comprising a selective LTB_4 receptor antagonist selected from 20 named structures and a COX-2 selective inhibitor selected from 11 named structures. Therefore, Applicants submit that claim 11 satisfies the written description requirement since all of the named compounds are listed in the specification. Claims 3, 4, 6, and 7 and claims 15 and 16 depend from claims 2 and 11, respectively, and satisfy the written description requirement for the same reasons as the independent claims. Applicants arguments are detailed below.

In claims 2 and 9 (as well as new independent claims 19 and 24), COX-2 selective inhibitors are selected from Taisho NS-398, meloxicam, flosulide, Merck MK-966, Merck L-752,860, and compounds of Formula I



wherein each of the substituents are defined, and selective LTB_4 receptor antagonists are claimed in terms of their function. In addition to the fact that COX-2 selective inhibitors and selective LTB_4 receptor antagonists were known at the time of the invention, the specification provides over 100 examples of specific compounds that selectively inhibit cyclooxygenase-2 (see pages 5-6 and 11-18) and over 40 examples of specific compounds that selectively antagonize leukotriene B_4 receptor (see pages 8-9). Relevant structural chemical formulas are therefore provided for a representative number of species. In addition, the specification provides a detailed definition regarding exactly what constitutes a "selective" cyclooxygenase-2 inhibitor and a "selective" leukotriene B_4 receptor antagonist:

> ...compounds which selectively inhibit cyclooxygenase-2 over cyclooxygenase-1. Preferably, the compounds have a cyclooxygenase-2 IC_{50} of less than about 0.5 μM, and also have a selectivity ratio of cyclooxygenase-2 inhibition over

> cyclooxygenase-1 inhibition of at least 50, and more preferably of at least 100. Even more preferably, the compounds have a cyclooxygenase-1 IC_{50} of greater than about 1 μM and more preferably of greater than 20 μM. Such preferred selectivity may indicate an ability to reduce the incidence of common NSAID-induced side effects.
>
> ...compounds which selectively antagonize a leukotriene B_4 receptor with an IC_{50} of less than about 10 μM. More preferably, the leukotriene B_4 receptor antagonists have an IC_{50} of less than about 1 μM.

With regard to the assertion in the Office action that "it is not possible to 'immediately envision' which compounds would be 'selective' inhibitors and/or antagonists because there is no common structural attributes and/or other identifying characteristics that can link together ***all*** of the compounds" (emphasis in original), Applicants respectfully submit that there is no requirement, statutory or otherwise, to describe the common attributes or characteristics that identify all or a substantial portion of a genus. While describing such common attributes may be one way to establish possession of the invention, it is not the only way. Applicants establish possession of the invention by disclosure of relevant structural chemical formulas, as specifically contemplated in the Guidelines and *Eli Lilly*, and therefore need not establish possession by description of common attributes.

As stated in *Eli Lilly*, 43 USPQ2d at 1406:

> In claims involving chemical materials, generic formulae usually indicate with specificity what the generic claims encompass. One skilled in the art can distinguish such a formula from others and can identify many of the species the claims encompass. Accordingly, such a formula is normally an adequate description of the claimed genus.

Therefore, in view of the structural formula provided for COX-2 selective inhibitors, Applicants submit that the pending claims satisfy the written description requirement with respect to the claimed COX-2 selective inhibitors.

The Office further noted that "...Applicant must provide some correlation between the structure and function of the claimed compounds...." Applicants believe that the Office stated this

particularly in connection with selective LTB_4 receptor antagonists, which are claimed functionally and 40 specific compounds are disclosed in the specification. To reiterate this point, the Office also alleged that COX-2 inhibitors and LTB_4 inhibitors could include an infinite number of compounds, such as antisense nucleotides, for which there is no support in the specification. Applicants submit that all of the claims refer to COX-2 selective inhibitors structurally, and thus exclude such possibility. Furthermore, with respect to selective LTB_4 receptor antagonists, Applicants submit that the specification provides 40 examples, and dependent claims also list a number of specific selective LTB_4 receptor antagonists that can be used. Furthermore, as stated in MPEP 2173.02, claim language must be analyzed, not in a vacuum, but in light of:

1) The content of the particular application disclosure;

2) The teachings of the prior art; and

3) The claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time invention was made.

Applicants note that the specification teaches the use of 40 LTB_4 receptor antagonists, which can all be grouped as small molecules. The prior art also teaches the use of small molecules, e.g., see paragraph [008], where it is stated:

> [C]ompounds which affect leukotriene B_4 have been described. U.S. Patent No. 5,384,318 describes substituted sulfonamides for the treatment of asthma. U.S. Patent No. 5,246,965 describes aryl ethers as leukotriene B_4 receptor antagonists.

Therefore, one skilled in the art can readily recognize which selective LTB_4 receptor antagonists are covered by the present claims. In view of the foregoing, Applicants respectfully submit that they have established possession of the invention by disclosure of relevant structural chemical formulas, and therefore need not establish possession by establishing a correlation between the structure and function.

With respect to claims 11, 15 and 16, Applicants respectfully request clarification of the rejection for lack of written description. Claim 11 is directed to a combination comprising a

selective LTB_4 receptor antagonist selected from 20 specific compounds and COX-2 selective inhibitor selected from 11 specific compounds, wherein all of the compounds are listed in the specification under preferred LTB_4 receptor antagonists and COX-2 selective inhibitors within Formula I. Hence, Applicants submit that claim 11 satisfies the written description requirement. Claims 15 and 16 depend from claim 11, and satisfy the written description requirement for the same reason as claim 11.

Rejection under 35 U.S.C. 112, Second Paragraph

Reconsideration is respectfully requested of the rejection of claims 1-4, 6, 11, and 15-18 under 35 U.S.C. § 112, second paragraph, for failing to particularly point out and distinctly claim the subject matter which applicant regards as invention.

As in the written description rejection, the Office reiterated that "a person of skill in the art would not be able to 'immediately envision all the possible chemical structures for either the COX-2 inhibitor or the LTB_4 receptor antagonist, which is further supported by the widely varying structures claimed by Applicants."

The Office has rejected claims 1-4, 6, 11, and 15-18 for failing to set forth the conditions under which the "selective activity" of the claimed selective cyclooxygenase-2 inhibitors and selective leukotriene B_4 antagonists is to be measured.

Claims 1, 17, and 18 have been cancelled rendering their rejection moot.

Applicants have defined selective cyclooxygenase-2 inhibitors as:

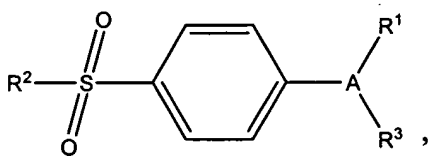
> . . .compounds which selectively inhibit cyclooxygenase-2 over cyclooxygenase-1. Preferably, the compounds have a cyclooxygenase-2 IC_{50} of less than about 0.5 μM, and also have a selectivity ratio of cyclooxygenase-2 inhibition over cyclooxygenase-1 inhibition of at least 50, and more preferably of at least 100. Even more preferably, the compounds have a cyclooxygenase-1 IC_{50} of greater than about 1 μM and more preferably of greater than 20 μM. Such preferred selectivity may

> indicate an ability to reduce the incidence of common NSAID induced side effects.[1]

> Furthermore applicants have defined selective leukotriene B_4 antagonists as:
>
> . . . compounds which selectively antagonize a leukotriene B_4 receptor with an IC_{50} of less than about 10 μM. More preferably, the leukotriene B_4 receptor antagonists have an IC_{50} of less than about 1 μM.[2]

Thus, applicants have disclosed a binding assay and the ranges of binding affinity which can be employed to indicate which compounds fall within the classification of either a selective cyclooxygenase-2 inhibitor or a selective leukotriene B_4 antagonist. Performing a binding assay to determine selectivity of a COX-2 inhibitor or an LTB_4 receptor antagonist at the time of the invention would have been considered routine by one skilled in the art. Moreover, the specification provides over 100 examples of specific compounds that selectively inhibit cyclooxygenase-2 and over 40 examples of specific compounds that are selective leukotriene B_4 receptor antagonist.

Claims 2 and 9 (as well as new independent claims 19 and 24) are directed to a combination and a pharmaceutical composition, respectively, comprising a COX-2 inhibitor selected from Taisho NS-398, meloxicam, flosulide, Merck MK-966, Merck L-752,860, and compounds of Formula I



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and a LTB_4 receptor antagonist. Claims 3, 4, 6, and 7 depend from claim 2.

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[1] Specification, page 7, line 29 to page 8, line 2.

[2] Specification page 8, lines 3-7.

Claim 11, as described under the written description section is directed to a combination comprising a LTB_4 receptor antagonist selected from 20 named compounds and a COX-2 inhibitor selected from 11 named compounds. Claims 15 and 16 are dependent from claim 11. Applicants submit that in view of the disclosure of claim 11, claims 11, 15 and 16 are not indefinite.

With respect to MK-886, the Office alleged that the specification is misleading because it lists MK-886 as a preferred LTB_4 receptor antagonist whereas in the Amendment D, dated December 17, 2003 Applicants disclaimed MK-886 as a LTB_4 receptor antagonist.

* Applicants are enclosing in a supplemental IDS an abstract by Noonan et al. (Prostaglandins, 44(6):543-54, Dec. 1992), which teaches that MK-886 has an IC_{50} of 13.33±7.91 μM for LTB_4 biosynthesis. However, from the abstract, it is not apparent how MK-886 inhibits LTB_4 synthesis, i.e., whether it is an LTB_4 receptor antagonist. Furthermore, due to a large standard deviation, it is unclear whether the IC_{50} falls under or above "about 10 μM" as defined in the instant specification. Due to these factors, Applicants submit that one of ordinary skill in the art could not determine with confidence whether MK-886 is a selective LTB_4 receptor antagonist as required by the instant specification. In view of the above, Applicants have deleted MK-886 from the claims with Amendment D, dated December 17, 2003, and have amended the specification with this Amendment to remove MK-886 from the listing of preferred LTB_4 receptor antagonists.

MPEP 2173.02 requires that definiteness of a claim be analyzed in light of the disclosure of the instant application, the teachings of the prior art, and the claim interpretation that would be given by one of ordinary skill in the art at the time the invention was made. Analyzed in this light, the required "selective activity" does not render the claims indefinite, and these claims satisfy the requirements of §112, second paragraph.

Furthermore, chemical compounds may be claimed by a name that adequately describes the material to one skilled in the art. See *Martin v. Johnson*, 454 F.2d 746, 172 USPQ 391 (CCPA 1972) and MPEP 2173.05(t).

In the pending claims, selective LTB_4 receptor antagonists are described as compounds which selectively antagonize a leukotriene B_4 receptor with an IC_{50} of less than about 10 μM. Coupled with the fact that LTB_4 receptor antagonists were already known in the art, Applicants submit that the name "selective LTB_4 receptor antagonist" adequately describes this material to one skilled in the art.

The Office has also rejected the claims for use of the term "selective" which the Office alleged is a relative term which renders the claims indefinite. Applicants respectfully disagree.

First, Applicants agree that the definition of a COX-2 inhibitor states that COX-2 inhibitors embrace compounds which selectively inhibit cyclooxygenase-2 over cyclooxygenase-1, and therefore, COX-2 inhibitors may include selective and non-selective COX-2 inhibitors. This is due to the fact that the term "embrace" can be seen as a synonym of "comprise." However, Applicants only claim selective COX-2 inhibitors. Preferably, such compounds have a cyclooxygenase-2 IC_{50} of less than about 0.5 μM, and also have a selectivity ratio of cyclooxygenase-2 inhibition over cyclooxygenase-1 inhibition of at least 50, and more preferably of at least 100. Even more preferably, the compounds have a cyclooxygenase-1 IC_{50} of greater than about 1 μM and more preferably of greater than 20 μM. Therefore, it is clear from the specification what the selective COX-2 inhibitors are, regardless of whether COX-2 inhibitors include non-selective inhibitors.

The same allegation was raised with the use of the term "embrace" in connection with the definition of an LTB_4 receptor antagonist, and Applicants note that the same argument as above applies in the case of selective LTB_4 receptor antagonists. Therefore, regardless of the fact that LTB_4 receptor antagonists can include selective and non-selective compounds, the claims only relate to selective LTB_4 receptor antagonists.

Rejections Under 35 U.S.C. § 103(a)

1. Claims 1-2, 9, 17 and 18 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Buchmann et al. (WO 94/04522) in view of Futaki et al. (Prostaglandins, 47:55-59, 1994). WO 94/04522 has the same translation as US Patent No. 5,559,134 (the '134 patent).

Claims 1, 17 and 18 were cancelled thereby rendering the rejection of these claims moot.

A. Buchmann does not Describe or Suggest Combination of an LTB_4 Receptor Antagonist and a **COX-2** Inhibitor, and could not have Contemplated such Combination with a **Selective COX-2** Inhibitor

Buchmann et al. relates to novel leukotriene B_4 antagonists and process for their production. In column 7, lines 58-65, Buchmann et al. mention briefly that:

> The new leukotriene-B_4 derivatives can also be used in combination, such as, e.g., with lipoxygenase inhibitors, **cyclooxygenase inhibitors**, glucocorticoids, prostacyclin agonists, thromboxane antagonists, leukotriene-D_4 antagonists, leukotriene-E_4 antagonists, leukotriene-F_4 antagonists, phosphodiesterase inhibitors, calcium antagonists, PAF antagonists or other known forms of treatment of the respective diseases. (Emphasis added.)

Futaki et al. disclose that NS-398 is a selective COX-2 inhibitor having similar potency to indomethacin, which is an NSAID. Furthermore, gastrointestinal lesions related to NS-398 following the oral administration of a dose of 1000 mg/kg were not significant, thus resulting in less gastrointestinal toxicity than is observed with NSAIDs. The Office alleged that Buchmann et al. teach the combination of an LTB4 antagonist and a COX-2 inhibitor and that a skilled artisan would have been motivated to use a selective COX-2 inhibitor as disclosed by Futaki et al. due to its reduced gastric toxicity. Applicants respectfully disagree.

Buchmann et al. claim priority to *August 25, 1992.* In the '134 patent, Buchmann et al. refer to "cyclooxygenase inhibitors" and not "cyclooxygenase-2 inhibitors" as the Office alleged. Applicants note that the one of the first times, if not the first time it was reported that an inducible cyclooxygenase enzyme exists was in the publication by Masferrer et al., *Proc. Natl. Acad. Sci. USA* Vol. 89, pp.3917-3921, *May 1992* (enclosed in the supplemental IDS). However,

that reference only acknowledges the existence of an inducible COX without naming the constitutive and inducible COX isoforms as COX-1 and COX-2.

Furthermore, Applicants turn the Office's attention to the meaning of the term "cyclooxygenase" as it was used prior to the discovery of COX-1 and COX-2.

> Formally, "cyclooxygenase" in general was thought to be responsible for the synthesis of prostaglandins involved in pain, inflammation and fever as well as cytoprotection in the stomach, hemostasis and blood flow in the kidneys. Later, two isoenzymes, cyclooxygenase-1 and cyclooxygenase-2 were discovered. It was postulated cyclooxygenase-1 to exist constitutively and to be responsible for cytoprotection and hemostasis whereas cyclooxygenase-2 is inducible and involved in pain, inflammation and fever. (Beubler E. abstract, *Wien Med Wochenschr.* 153(5-6):95-99, 2003, enclosed in the supplemental IDS.)

In addition, Futaki *et al.* state in the abstract that "NS-398 is the first documented agent to have selective inhibition for COX-2." Futaki et al. article was published in 1994. Therefore, in view of the use of the term "cyclooxygenase" and the later time of publication of the first documented agent exhibiting selective inhibition for COX-2, Applicants submit that Buchmann et al. did not describe or suggest combination of an LTB_4 receptor antagonist and a COX-2 inhibitor, and could not have contemplated the combination of an LTB_4 receptor antagonist and a COX-2 selective inhibitor at the time of the filing of their patent.

B. Neither Buchmann et al. nor Futaki et al. Provides any Motivation to Make the Modification

As noted in A. above, Buchmann et al. did not provide any motivation to combine an LTB4 receptor antagonist with a COX-2 inhibitor, let alone a selective COX-2 inhibitor. At the time of filing the application for the '134 patent, one of the most common cyclooxygenase inhibitors was ibuprofen, and one skilled in the art might have interpreted this paragraph as a suggestion to combine the LTB4 receptor antagonists with ibuprofen or any of the multitude of

compounds encompassed by the 11 classes described therein. Such a combination is not a suggestion to combine with a COX-2 inhibitor. Although Futaki et al. suggests that one selective COX-2 inhibitor caused less gastric lesions than an NSAID, that would not have motivated one skilled in the art to combine NS-398 with other agents such as selective LTB4 receptor antagonists. Therefore, the necessary motivation to make the claimed invention is entirely lacking in the cited references and applicants submit that the claims are unobvious over the cited references.

C. There is Evidence of no Reasonable Expectation of Success

Buchmann et al. state that their new LTB4 antagonists can be used to treat diseases of internal organs with inflammatory processes (column 7, lines 50-52). The only mention of use of the antagonists in combination with another agent appears at column 7, lines 58-65, where Buchmann et al. mention briefly that:

> [t]he new leukotriene-B_4 derivatives can also be used in combination, such as, e.g., with lipoxygenase inhibitors, **cyclooxygenase inhibitors**, glucocorticoids, prostacyclin agonists, thromboxane antagonists, leukotriene-D_4 antagonists, leukotriene-E_4 antagonists, leukotriene-F_4 antagonists, phosphodiesterase inhibitors, calcium antagonists, **PAF antagonists** or other known forms of treatment of the respective diseases. (Emphasis added.)

Buchmann et al. provide no further guidance as to selection of an agent from these classes and do not name any specific compounds of these classes.

Applicants submit that there was no reasonable expectation of success in making combinations as mentioned in Buchmann et al. because a subset of compounds encompassed by the 11 classes described therein were not effective in several scenarios of inflammation, in which LTB4 receptor antagonists showed effectiveness. Specifically, Applicants point to two abstracts, which look at the efficacy of LTB4 antagonists or PAF antagonists administered singly in airway inflammation and sensory neuron inflammation (Richards et al., *Annals of the New York*

Academy of Sciences, Vol. 629, issue 1, p.274-287, 1991, and Iwamoto et al., *J Immunol.*, 151(4):2116-2123, Aug. 15, 1993, enclosed in the supplemental IDS).

Richards et al. state that lung eosinophilia, which contributes to airway inflammation was not prevented by two tested PAF antagonists but was inhibited by LTB4 antagonists. Iwamoto et al. abstract discloses that an LTB4 antagonist decreased substance P-induced neutrophil and eosinophil infiltration into mouse skin, which contributes to inflammation. In contrast, a PAF antagonist affected neither substance P-induced neutrophil nor eosinophil infiltration. Iwamoto et al. conclude that LTB4 antagonists may be useful in preventing neurogenic inflammation.

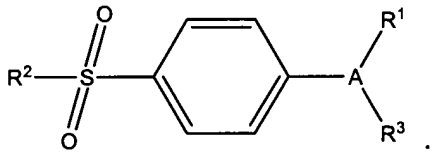
Based on these two abstracts, Applicants submit that there would have been no reasonable expectation of success in combining LTB4 antagonists and PAF antagonists as suggested by Buchmann et al., and that one skilled in the art having such evidence before him would not have had a reasonable expectation that any suggested agent would have added to the effectiveness of the LTB4 receptor antagonist. In view of that, Applicants note that there would have been no reasonable expectation of success in combining other agents suggested by Buchmann et al., such as LTB4 antagonists and cyclooxygenase inhibitors.

In view of the above, Applicants note that one skilled in the art would not have been motivated to combine the LTB4 antagonists taught by Buchmann et al. with NS-398 as taught by Futaki et al., and that there would not have been any reasonable expectation of success in doing so. Accordingly, withdrawal of the rejection of claims 2 and 9 under 35 U.S.C. § 103(a) over Buchmann et al. in view of Futaki et al. is respectfully requested.

2. Claims 1-2 and 6-9 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Ducharme et al. (US Patent No. 5,474,995) in view of Rainsford, K.D. (Agents and Actions, 39: C24-C26, 1993).

Claim 1 has been cancelled. Claims 2 and 9 are directed toward a combination of two specific compounds: a selective LTB_4 receptor antagonist described functionally, and a COX-2

selective inhibitor selected from Taisho NS-398, meloxicam, flosulide, Merck MK-966, Merck L-752,860, and compounds of Formula I



Claims 6 and 7 depend from claim 2. Claim 8 has been withdrawn.

Ducharme et al. teach the substitution of cyclooxygenase-2 inhibitors for conventional NSAIDs in preparations where they are co-administered with other agents or ingredients. Rainsford teaches the administration of a 5-lipoxygenase inhibitor, MK-886 at 3-5 hours and 15 minutes prior to the administration of indomethacin or aspirin in order to reduce the number and area of gastric lesions in cholinomimetic mice. Firstly, as stated under the indefiniteness rejection section, the Applicants have amended the specification to delete MK-866 from the list of preferred LTB_4 receptor agonists. MK-886 was deleted from the claims with Amendment D, dated December 17, 2003. Furthermore, even Rainsford referred to MK-886 as a 5-lipoxygenase inhibitor and not a selective LTB_4 receptor agonist.

Secondly, Rainsford et al. stated in the discussion that "[I]t appears essential to dose the 5-LO inhibitor, MK-886, for 3-5h, and 0.25-0h to reduce GI mucosal lesions." In addition, on page C25 Rainsford states that "[N]o effects occurred when MK-886 was given as a single dose either at 0h or 3, 4, or 5h earlier with these NSAIDs (no data)." Therefore, one skilled in the art would not have been motivated to combine a COX-2 selective inhibitor with MK-886, let alone a selective LTB_4 receptor antagonist. Furthermore, there would have been no reasonable expectation that the combination of a selective COX-2 inhibitor and a selective LTB_4 receptor antagonist would be successful based on the teachings of Ducharme and Rainsford.

Double Patenting Rejections

Claims 1-4, 7, 9, 11, 15-18 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 of US Patent No. 6,172,096 and over claims 1-11 of US Patent No. 6,617,345.

In addition, the Office has provisionally rejected claims 1-4, 6, 7, 9, 11, 15-18 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of US Published application US 2004/0106668.

Applicants respectfully request reconsideration of the nonstatutory double patenting rejection of claims 2-4, 7, 9, 11, 15 and 16. Applicants submit herewith two Terminal Disclaimers in accordance with 37 CFR 1.130(b) and 37 CFR 1.321(c) to obviate the rejection and expedite allowance of all of the pending claims. Applicants traverse the various findings, upon which the Office relies, in making the nonstatutory double patenting rejections. However, Applicants will not burden the Office with arguments at this time in view of the fact that the rejections are obviated by the submission of the terminal disclaimers. Applicants respectfully request the double patenting rejections be withdrawn.

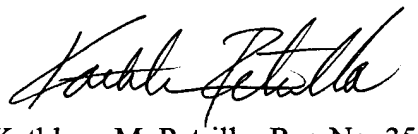
Conclusion

In light of the foregoing, the Applicants respectfully request entry of the claim amendments and withdrawal of the claim rejections. The Examiner is invited to contact the undersigned attorney should any issues remain unresolved.

Applicants request an extension of time to and including January 27, 2005 for filing a response to the above-mentioned Office action. A check in payment of the applicable extension fee and excess claim fee is enclosed.

The Commissioner is hereby authorized to charge any deficiency or overpayment of the required fee to Deposit Account No. 19-1345.

Respectfully submitted,



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